



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ulf TILSTAM et al.

Examiner: Howard V. Owens, Jr.

Serial No.: 09/471,040

Group Art Unit: 1623

Filed: December 23, 1999

Title: PROCESS FOR THE PRODUCTION OF FLUDARABINE-PHOSPHATE
LITHIUM, SODIUM, POTASSIUM, CALCIUM AND MAGNESIUM SALTS
AND PURIFICATION PROCESS FOR THE PRODUCTION OF
FLUDARABINE-PHOSPHATE AND FLUDARABINE-PHOSPHATE WITH A
PURITY OF AT LEAST 99.5%

REPLY

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following is responsive to the office action of July 5, 2005.

Attached hereto is a Declaration of Drs. Wessa and Rabe. The facts established by this declaration, it is respectfully submitted, overcome the examiner's rejection under 35 USC 103.

This declaration, among other things, establishes that the Montgomery process as carried out in its Example II does not produce a fludarabine phosphate product meeting the purity requirements of the claims.

The declaration also establishes why the examiner's postulated recycle/repetition of column purification steps or routine purification techniques in general would not produce a fludarabine phosphate of the purity of the claims. These conclusions are based on scientific facts and must be accorded proper weight by the examiner.